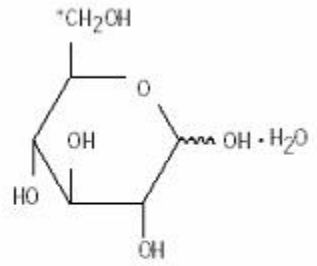
RINGERS AND DEXTROSE - dextrose monohydrate, sodium chloride, calcium chloride and potassium chloride injection, solution

Baxter Healthcare Corporation

DESCRIPTION

Ringer's and 5% Dextrose Injection, USP is sterile, nonpyrogenic solution for fluid and electrolyte replenishment and caloric supply in a single dose container for intravenous administration. Each 100 mL contains 5 g Dextrose Hydrous, USP*; 860 mg of Sodium Chloride, USP (NaCl); 33 mg of Calcium Chloride, USP ($CaCl_2 \cdot 2H_2O$); and 30 mg of Potassium Chloride, USP (KCl). It contains no antimicrobial agents. The pH is 4.0 (3.5 to 6.5).



D-Glucopyranose monohydrate

Ringer's and 5% Dextrose Injection, USP administered intravenously has value as a source of water, electrolytes, and calories. One liter has an ionic concentration of 147.5 mEq sodium, 4.5 mEq calcium, 4 mEq potassium, and 156 mEq chloride. The osmolarity is 561 mOsmol/L (calc). Normal physiologic range is approximately 280 to 310 mOsmol/L. Administration of substantially hypertonic solutions may cause vein damage. The caloric content is 170 kcal/L.

The VIAFLEX plastic container is fabricated from a specially formulated polyvinyl chloride (PL 146 Plastic). The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e.g., di-2-ethylhexyl phthalate (DEHP), up to 5 parts per million. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies.

CLINICAL PHARMACOLOGY

Ringer's and 5% Dextrose Injection, USP has value as a source of water, electrolytes, and calories. It is capable of inducing diuresis depending on the clinical condition of the patient.

INDICATIONS AND USAGE

Ringer's and 5% Dextrose Injection, USP is indicated as a source of water, electrolytes and calories.

CONTRAINDICATIONS

Solutions containing dextrose may be contraindicated in patients with known allergy to corn or corn products

WARNINGS

Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there exists edema with sodium retention.

Ringer's and 5% Dextrose Injection, USP should be used with great care, if at all, in patients with hyperkalemia, severe renal failure, and in conditions in which potassium retention is present.

Ringer's and 5% Dextrose Injection, USP should not be administered simultaneously with blood through the same administration set because of the likelihood of coagulation.

The intravenous administration of Ringer's and 5% Dextrose Injection, USP can cause fluid and/or solute overloading resulting in dilution of serum electrolyte concentrations, overhydration, congested states, or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injection. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injection.

In patients with diminished renal function, administration of Ringer's and 5% Dextrose Injection, USP may result in sodium or potassium retention.

PRECAUTIONS

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation.

Caution must be exercised in the administration of Ringer's and 5% Dextrose Injection, USP to patients receiving corticosteroids or corticotropin.
Ringer's and 5% Dextrose Injection, USP should be used with caution in patients with overt or subclinical diabetes mellitus.

Carcinogenesis and Mutagenesis and Impairment of Fertility
Studies with Ringer's and 5% Dextrose Injection, USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Pregnancy Category C
Animal reproduction studies have not been conducted with Ringer's and 5% Dextrose Injection, USP. It is also not known whether Ringer's and 5% Dextrose Injection, USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Ringer's and 5% Dextrose Injection, USP should be given to a pregnant woman only if clearly needed.

Nursing Mothers
It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Ringer's and 5% Dextrose Injection, USP is administered to a nursing woman.

Pediatric Use
Safety and effectiveness of Ringer's and 5% Dextrose Injection, USP in pediatric patients have not been established by adequate and well controlled trials, however, the use of ringer's and dextrose solutions in the pediatric population is referenced in the medical literature. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population. In very low birth weight infants, excessive or rapid administration of dextrose injection may result in increased serum osmolality and possible hemorrhage

Geriatric Use
Clinical studies of Ringer's and 5% Dextrose Injection, USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or drug therapy.
Do not administer unless solution is clear and the seal is intact

ADVERSE REACTIONS
Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation, and hypervolemia.
If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

DOSAGE AND ADMINISTRATION
As directed by a physician. Dosage is dependent upon the age, weight and clinical condition of the patient as well as laboratory determinations.
Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit.
All injections in VIAFLEX plastic containers are intended for intravenous administration using sterile equipment.
Additives may be incompatible. Complete information is not available. Those additives known to be incompatible should not be used. Consult with pharmacist, if available. If, in the informed judgement of the physician, it is deemed advisable to introduce additives, use aseptic technique. Mix thoroughly when additives have been introduced. Do not store solutions containing additives.

HOW SUPPLIED
Ringer's and 5% Dextrose Injection, USP in VIAFLEX plastic containers is available as shown below:

Code	Size (mL)	NDC
2B2064	1000	NDC 0338-0111-04
2B2063	500	NDC 0338-0111-03

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. It is recommended the product be stored at room temperature (25°C): brief exposure up to 40°C does not adversely affect the product.

DIRECTIONS FOR USE OF VIAFLEX PLASTIC CONTAINER

Warning: Do not use plastic containers in series connections. Such use could result in air embolism due to residual air being drawn from the primary container before administration of the fluid from the secondary container is completed.

To Open

Tear overwrap down side at slit and remove solution container. Some opacity of the plastic due to moisture absorption during the sterilization process may be observed. This is normal and does not affect the solution quality or safety. The opacity will diminish gradually. Check for minute leaks by squeezing inner bag firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below.

Preparation for Administration

1. Suspend container from eyelet support.
2. Remove plastic protector from outlet port at bottom of container.
3. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Additives may be incompatible.

To add medication before solution administration

1. Prepare medication site.

2. Using syringe with 19 to 22 gauge needle, puncture medication port and inject.

3. Mix solution and medication thoroughly. For high density medication such as potassium chloride, squeeze ports while ports are upright and mix thoroughly.

To add medication during solution administration

1. Close clamp on the set.

2. Prepare medication site.

3. Using syringe with 19 to 22 gauge needle, puncture resealable medication port and inject.

4. Remove container from IV pole and/or turn to an upright position.

5. Evacuate both ports by squeezing them while container is in the upright position.

6. Mix solution and medication thoroughly.

7. Return container to in use position and continue administration.

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